January 9, 2002

MEMORANDUM:

SUBJECT: **Lindane** (009001): **Revised Dietary Risk and Exposure Estimate For Lindane Through Subsistence Diets for Indigenous People of Alaska. DP Barcode #** D280076. **Reregistration Case** 0315. **MRID No.** none.

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INTRODUCTION:

The occurrence of organochlorine contaminants in the Arctic has been documented in several studies. A variety of organochlorine contaminants including lindane has been found in terrestrial, freshwater, and marine habitats. This contamination is primarily the result of long range continental transport through the movement of the air and ocean currents. The source of the lindane is unknown but most likely reflects past uses other than seed treatment. Lindane is the gamma isomer of hexachlorocyclohexane (HCH) and is also known as gamma isomer of benzene hexachloride (BHC). Technical HCH contained the alpha, beta, delta, and gamma isomers but was banned in the United States in the 1970s. The composition of technical HCH varied widely, but often the alpha isomer was the predominant isomer. Lindane (gamma isomer of HCH) remains registered in the U.S. as a seed treatment only. Studies have shown higher concentrations of lindane and total HCH in some wildlife from west to east. This is thought to be due to the direction of air currents.

The Indigenous Peoples of the Arctic region of the U.S. (Alaska) rely heavily on subsistence diets as their food source. Thus, it is appropriate for the Agency to perform a supplementary dietary risk and exposure assessment to assess the risk to the Indigenous People from worldwide use and manufacture of lindane. This memorandum serves to update the previous dietary assessment performed for the indigenous people of Alaska by incorporating new information pertaining to subsistence meat intake by children. Because the annual harvest rates were divided by 365 to obtain daily harvest rates, and the daily intake rates used in the assessment no acute dietary exposure analysis was conducted.

EXECUTIVE SUMMARY:

- Using subsistence food harvest amounts, total HCH residues in traditional foods, and adjusting the HCH exposure (since lindane represents between 3 and 15 % of total HCH residues) to obtain lindane exposure results in an range of exposures of 0.0039 - 0.04231 mg/day. Thus dividing this exposure by 70 kg (weight of adult male) would result in a range of exposures for the male Indigenous People to lindane of 0.000055 - 0.00060 mg/kg bw/day which is 3 - 38 % cPAD and below HED's level of concern (cPAD = 0.0016 mg/kg body weight/day). Dividing the range of exposures of 0.0039 - 0.04231 mg/day by 60 kg (weight of adult female) would result in a range of exposures for the female Indigenous People to lindane of 0.000064 - 0.00071 mg/kg bw/day which is 4 - 44 % cPAD and below HED's level of concern. The adult intake amounts from each community were adjusted by a factor of 0.53 to correct for the difference in subsistence meat intake between children and adults. These adjusted child intake amounts were then used to calculate a range of lindane dietary risk estimates for children resulting from subsistence food consumption of 13 % to 138 %. The child risks also incorporates the range of potential lindane residues relative to total HCH (i.e., 3-15%).

- HED believes these estimates may be an overestimate of dietary risk since dietary intake equaled harvest (i.e., adults consume up to 2.4 pounds of subsistence meat per day and children consume up to 1.3 pounds of subsistence meat per day). Harvest amounts were used from the three communities of approximately 180 Alaskan communities with the highest seal harvest, highest whale harvest, and the highest walrus harvest. This does not take into account portions of the harvest which were discarded or used for non-dietary purposes. Also, the maximum detected HCH residue concentration was used in the calculation of the HCH exposure in the respective subsistence food item. For example, the beluga whale blubber HCH concentration was assumed for the entire harvest (and consumption) amount and not taking into account other tissues consumed which may have had much lower residue amounts.

DETAILED CONSIDERATIONS:

Memoranda providing details of relevant toxicological information include the HIARC report dated 6/18/01 and the FQPA Safety Factor Committee report dated 8/2/00.

The acute and chronic FQPA safety factors of 10X were reduced to 3X (see FQPA Safety Factor Document, 8/2/00). A reference dose (RfD) which includes the FQPA safety factor (typically 10X, 3X or 1X) is defined as the Population Adjusted Dose (PAD). Doses and endpoints for dietary risk assessment are presented in Table 1.

The chronic population adjusted dose (cPAD) for lindane is 0.0016 mg/kg/day. The cPAD is the chronic RfD of 0.0047 mg/kg/day divided by the FQPA factor of 3 yielding a cPAD of 0.0016 mg/kg/day. The chronic endpoint and dose is listed in Table 1 below.

The Agency used the subsistence food harvest amounts of nearly 180 communities from the Community Profile Database Version 3.11 dated 3/27/01 from the Alaska Department of Fish and Game Division of Subsistence as subsistence food intake rates. This is a database which includes the harvest of subsistence foods in Alaskan communities from the years 1990-2001. From personal communication with Mr. Roland Shanks from the Alaska Inter-Tribal Council it was determined that usually only two of the following marine mammals (walrus, seal, and whale) are harvested in significant amounts. Therefore, HED used the community with the highest representative seal harvest, the community with the highest walrus harvest, and the community with the highest whale harvest. Generally polar bear and another marine mammal were also used along with the harvest of significant amounts of fish, land mammal, and birds from the corresponding Alaskan community. HED used the per capita harvest amount as the human intake amount which would be a conservative estimate since some of the harvest would be used for non-human food purposes and waste. Variability in intake amounts have been shown between tribal communities within Western Canada. It is therefore likely that there would be variability in intake rates between tribal communities in Alaska depending on the availability of fish and game meat. The adult intake amounts were adjusted by a factor of 0.53 to obtain the intake amount for children. This factor was derived from a publication (Heller, 1966)[1].

Population	Community		
	Pt. Hope	Notak	Shungnak
Adult Males	438 grams	429 grams	573 grams
Children 7-12 years old	230 grams	230 grams	303 grams
Child's % of Adults Subsistence Meat Consumption	**52.5**	**53.6**	**52.9**

The Agency coupled this dietary intake data with organochlorine residue data which were obtained from Dr. Laurie Chan of McGill University in Canada via personal communication. The report gave analytical results of the samples for total hexachlorocyclohexane (HCH) and not the individual isomers. Using this value would overestimate the risk estimate by including other isomers of HCH in addition to lindane which is the gamma isomer. The other isomers of HCH may be environmental concentrations resulting from previous use of technical HCH. Therefore, a factor of 0.03 or 0.15 was used to multiply the total HCH exposure to account for exposure to lindane only. The factor of 0.03 or 0.15 was derived from a study conducted by McGill University (Receveur, 1998) in which lindane and total HCH was measured. Lindane accounted for <3 to 15 % of the total HCH present in samples of animal tissue.

The data included analytical results for total HCH in numerous traditional foods. The report listed a maximum residue value of 20 ng/g of total HCH for walrus blubber, 215 ng/g for ringed seal blubber, 9 ng/g for moose flesh, 1 ng/g for caribou flesh, 2 ng/g for muskox flesh, 4 ng/g for Dall sheep flesh, 26 ng/g for salmon flesh, 20 ng/g for whitefish flesh, 6 ng/g for arctic char flesh, 3 ng/g for arctic grayling flesh, 1 ng/g for cisco flesh, 3 ng/g for lake trout flesh, 348 ng/g for ooligan flesh (which in this assessment will be used for cod, smelt, and herring),10 ng/g for polar bear flesh, 391 ng/g for beluga whale blubber, 7 ng/g for eider flesh, 1 ng/g for goose flesh, 4 ng/g for gull eggs, and 10 ng/g preserved soapberries. Multiplying the maximum HCH concentration in the traditional food by the harvest amount (converted to grams/person/day) results in the exposure to HCH from the traditional food item. Multiplying the residue concentration by the appropriate traditional food amount for each community would result in an estimated exposure to lindane from the consumption of traditional food. Within each community, the individual exposures are then summed for a total exposure to lindane in traditional food.

Summing the exposures from the subsistence food sources in Community 1 (highest total exposure of the three communities) amounts to an exposure to total HCH of 282,065 ng/day. When converted to mg/day this exposure becomes 0.282065 mg/day. The total HCH exposure of 0.282065 mg/day must be adjusted by the factor of 0.03 or 0.15 (since lindane represents between 3 and 15 % of total HCH residues) to obtain the lindane only exposure yielding a lindane exposure for Community 1 of 0.0039 - 0.04231 mg/day. This value must be divided by the weight of an adult male/female in kilograms for comparison to the chronic Population Adjusted Dose (cPAD). The units of the cPAD are mg/kg body weight/day. The cPAD for lindane is 0.0016 mg/kg body weight/day. Dividing 0.04231 (assuming lindane is 15% of total HCH) mg/day by 70 kg (male weight) would result in an exposure of 0.0006 mg/kg/day. Comparing this exposure to the lindane cPAD of 0.0016 mg/kg body weight/day reveals that the exposure of the male Indigenous People to lindane is 38 % cPAD and thus, would be below HED's level of concern. The range of lindane dietary risk estimates for adult males resulting from subsistence food consumption is 3 % to 38 %. Dividing 0.04231 mg/day by 60 kg (female weight) would result in an exposure of 0.0007 mg/kg/day. Comparing this exposure to the lindane cPAD of

0.0016 mg/kg body weight/day reveals that the exposure of the female Indigenous People to lindane is 44 % cPAD and thus, would be below HED's level of concern. The range of lindane dietary risk estimates for adult males resulting from subsistence food consumption is 4 % to 44 %. The adult intake amounts from each of the three communities were adjusted by a factor of 0.53 to incorporate the difference in subsistence meat intake between children and adults[1]. These adjusted child intake amounts were then multiplied by the respective HCH residue amount to derive a total HCH exposure from each subsistence meat source. The total HCH residue amount was then multiplied by 0.03 and 0.15 to obtain the lindane residue amount. The lindane residue amount was then divided by 10 kg (weight of child), and then by 0.0016 (cPAD) to obtain the % cPAD which was occupied by the lindane exposure from subsistence foods (Table 3). The range of lindane dietary risk estimates for children resulting from subsistence food consumption is 13 % to 138 %.

Table 1. Lindane: Toxicological Doses and Endpoints for Dietary Risk Assessment.

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY TYPE/ MRID
Chronic Dietary	NOAEL=10 ppm (0.47 mg/kg/day) UF = 100 FQPA = 3X	LOAEL is 100 ppm (4.81 mg/kg/day) periacinar hepatocyte hypertrophy, increased liver/spleen weight, and increased platelets	Chronic Feeding and Carcinogenicity in Rats 41094101 41853701 42891201
	Chronic RfD = 0.0047 mg/kg/day **Chronic Population Adjusted Dose (cPAD) = 0.0016 mg/kg/day**		

cPAD = RfD/FQPA Safety Factor.

Table 2. Community Harvest of Traditional Foods and total HCH residues.

Traditional Food	Total HCH Residues (ng/g)	Community 1 Harvest (grams/person/day)	Community 2 Harvest (grams/person/day)	Community 3 Harvest (grams/person/day)
Polar Bear	10	9	26	16
Seal	215	39	500	46
Whale	391	697	----	271
Walrus	20	----	22	315
Caribou	1	123	103	221
Moose	9	----	81	----
Muskox	2	13	----	----
Dall Sheep	4	20	----	----
Salmon	26	28	116	----
Arctic Char	6	----	10	----
Lake Trout	3	100	----	----
Arctic Grayling	3	6	----	6
Whitefish	20	----	14	19
Cod	Residue from ooligan flesh used - 348 ng/g	----	18	----
Smelt		----	10	17
Herring		----	22	----
Cisco	1	39	8	19
Goose	1	14	15	14
Duck	7	----	12	----
Berries	10	----	15	----
Total HCH Exposure		**282,065 ng/day**	**130,045 ng/day**	**128,879 ng/day**

Table 3. Assumed Total Dietary Intake of Lindane (gamma-HCH) and Estimated Risk for Indigenous Children.

% Total HCH which is Lindane	Community 1 (mg/kg/day)/%cPAD[a]	Community 2 (mg/kg/day)/%cPAD	Community 3 (mg/kg/day)/%cPAD
3% Lindane	0.00045/28	0.00021/13	0.00021/13
15% Lindane	0.0022/138	0.0010/65	0.0010/65

[a] Example calculation: Exposure = 0.282 mg/day * 0.15 or 0.03 * 0.53 / 10 kg = 0.0022 mg/kg/day (15% lindane) or 0.00045 mg/kg/day (3% lindane).

Table 4. Assumed Total Dietary Intake of Lindane (gamma-HCH) and Estimated Risk for Indigenous Adult Males.

% Total HCH which is Lindane	Community 1 (mg/kg/day)/%cPAD[a]	Community 2 (mg/kg/day)/%cPAD	Community 3 (mg/kg/day)/%cPAD
3% Lindane	0.00012/8	0.000056/3	0.000055/3
15% Lindane	0.00060/38	0.00028/17	0.00027/17

Table 5. Assumed Total Dietary Intake of Lindane (gamma-HCH) and Estimated Risk for Indigenous Adult Females.

% Total HCH which is Lindane	Community 1 (mg/kg/day)/%cPAD[a]	Community 2 (mg/kg/day)/%cPAD	Community 3 (mg/kg/day)/%cPAD
3% Lindane	0.00014/9	0.000065/4	0.000064/4
15% Lindane	0.00071/44	0.00033/20	0.00032/20

Table 6. Assumed Total Dietary Intake of Lindane (gamma-HCH) and Estimated Risk.

Population Subgroup	Body Weight (kg)	Estimated Lindane Exposure (mg/kg/day)	% cPAD
Adult male	70	0.000055 - 0.0006	3-38
Adult female	60	0.000064 - 0.00071	4-44
Children	10	0.0002 - 0.0022	13-138

References:

[1] Heller, C., 1966. Meat Consumption at Three Northern Eskimo Villages. Environment of the Cape Thompson Region, Alaska. Wilimovsky, Norman, & Wolfe, John, Editors. United States Atomic Energy Commission. pp. 1109-1111.

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